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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,520	01/17/2002	Qing Qi	CS13-PT001	6223
3624	7590	10/01/2004	EXAMINER	
VOLPE AND KOENIG, P.C. UNITED PLAZA, SUITE 1600 30 SOUTH 17TH STREET PHILADELPHIA, PA 19103			PRATS, FRANCISCO CHANDLER	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/031,520

Applicant(s)

QI ET AL.

Examiner

Francisco C Prats

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 1,3-6,8,10-13,15,17-20,22,24-27,29,31-34,36,38-41,43,45-48,50,52-55,57-61 and 63-71.

Continuation of Disposition of Claims: Claims rejected are 1,3-6,8,10-13,15,17-20,22,24-27,29,31-34,36,38-41,43,45-48,50,52-55,57-61 and 63-71.

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DETAILED ACTION

The amendment filed July 14, 2004, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claims 1, 3-6, 8, 10-13, 15, 17-20, 22, 24-27, 29, 31-34, 36, 38-41, 43, 45-48, 50, 52-55, 57-61 and 63-71 are pending and are examined on the merits.

Claim Rejections - 35 USC § 103

Claims 1, 3-6, 8, 10-13, 15, 17-20, 22, 24-27, 29, 31-34, 36, 38-41, 43, 45-48, 50, 52-55, 57-61 and 63-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shinpo et al (JP 58-128322)).

Shinpo et al disclose a glycoprotein having anti-cancer properties which can be prepared from Spirulina. As also discussed above, The prior art glycoprotein is disclosed at pages 3 and 4 as being prepared by a process comprising the steps of:

- dispersing 500 g powdered algal bodies in 5 L water (a 1:10 ratio),
- performing a hot water extraction at 95 to 100°C for 20 to 30 minutes,

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- centrifuging the hot water extract and obtaining the supernatant,
- cooling the supernatant to 50°C and concentrating the solution under reduced pressure,
- filtering the extract through a semipermeable membrane,
- subjecting the filtrate to chromatography, and
- freeze drying the resulting product.

Thus, the product-by-process claims and the process claims differ from Shinpo in not disclosing the step of adjusting the pH to 3.8-4.2 as recited in the claims as amended. However, as also discussed above, Shinpo discloses that weak acid or alkali may be used in the initial extraction step. See page 3 of translation. ("The medium used in [the] above extraction is not limited to hot water; there are no impediments to using water with a weak acid or alkali.") The artisan of ordinary skill clearly would have recognized that performing extractions at different pH values would affect the properties of the resulting product. Thus, recognizing that extraction pH was a result-effective parameter, the artisan of ordinary skill clearly would have been motivated to have optimized that parameter to have produced a *Spirulina* hot water extract having maximal therapeutic efficacy. Therefore, the determination of a

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suitable pH for the acidic extraction of *Spirulina* according to the methods of Shinpo clearly must be considered an obvious optimization of Shinpo's process, and therefore unpatentable under § 103(a). Absent some demonstration of an unexpected result coming from the claimed extraction pH, a holding of *prima facie* obviousness must be maintained.

Lastly, as to the claims' requirement of a neutralizing step, note specifically that after initial extraction, Shinpo discloses bringing the extract to a volume of 1 L using distilled water, prior to subsequent purification steps. See sentence spanning pages 3 and 4 of the translation. While it is not clear that the solution was neutralized precisely to pH 7, one of ordinary skill clearly would have been motivated by this disclosure in Shinpo to have neutralized the solution. A holding of obviousness over the cited claims is clearly required.

Response to Arguments

All of applicant's argument has been fully considered with respect to the pending ground of rejection, but is not persuasive of error. It is noted that Shinpo does not explicitly disclose a cell wall breaking step. However, Shinpo's process subjects the cells to relatively vigorous

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treatment by hot water, which would have been expected to have broken at least a few cell walls, absent direct evidence to the contrary. Moreover, it is respectfully pointed out that applicant's claims are directed to products not processes. Thus, while cell wall breaking may result in improved yields as urged by applicant, it is not clear on the current record that the claimed cell wall breaking step results in a product any different than that suggested by Shinpo.

Specifically, on the current record it is clear that Shinpo considers a hot water-extracted, acid-soluble product from algae, including *Spirulina*, to be desirable as a carcinostatic agent. See page 3 of translation. ("The medium used in [the] above extraction is not limited to hot water; there are no impediments to using water with a weak acid or alkali.") Thus, while Shinpo does not necessarily disclose an embodiment which anticipates the claims as amended, Shinpo clearly considers a product which would result from the claimed process steps to be desirable.

Lastly, it is noted, as argued by applicant, that Shinpo purifies only a single active component from the disclosed therapeutic extract. However, this does not necessarily mean that Shinpo's acid-soluble, hot water extract lacks other therapeutically active components. In short, there is no direct

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record evidence that Shinpo's extract lacks any of the components present in the claimed extracts. Moreover, in view of the fact that the claims do not require the presence of any specific ingredients, applicant's argument is not directed to a limitation actually present in the claims. In sum, because Shinpo considers a hot water-extracted, acid-soluble product from algae, including *Spirulina*, to be desirable as a carcinostatic agent, the claimed hot water-extracted, acid-soluble product from *Spirulina* must be considered obvious under § 103(a).

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened

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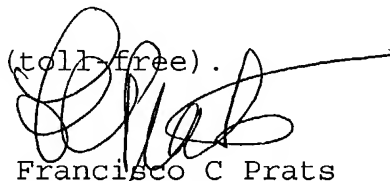
statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 571-272-0921. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Francisco C Prats
Primary Examiner
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FCP